K060765

SEP - 6 2006

5.0 510(k) Summary

Submitter:	HemoCue AB Box 1204 Ängelholm, Sweden SE-262 23 +46 431 45 82 00 (Telephone) +46 431 45 82 25 (FAX)
Contact:	Mr. Allan White (Official Correspondent) HemoCue, Inc. 40 Empire Drive Lake Forest, CA 92630-2244 (800) 881-1611 x110 (Telephone) (949) 859-3066 (FAX) allan@hemocue.com
Date of Preparation:	March 17, 2006
Proprietary Name:	HemoCue Glucose 201 RT system
Classification Name:	Glucose Dehydrogenase, Glucose test system (21 CFR § 862.1345), Product code: LFR
Common Name:	HemoCue Glucose 201 RT system
Equivalent to:	HemoCue AB claims substantial equivalence to the current legally marketed HemoCue Glucose 201 system (K020935)

Description
The HemoCue Glucose 201 RT system consists of a small and portable analyzer (photometer) and plastic microcuvettes. The HemoCue Glucose 201 RT Microcuvette contains reagents deposited on its inner walls and serves both as a pipette and as a measuring cuvette. A blood sample of approximately 4 µL is drawn into the cavity by capillary action. The filled microcuvette is inserted into the HemoCue Glucose 201 RT Analyzer. The measurement takes place in the analyzer in which the transmittance is measured and the absorbance and glucose level is calculated.

Intended use
The HemoCue Glucose 201 RT system is used for quantitative determination of glucose in whole blood supplementing the clinical evidence in the diagnosis and treatment of patients with diabetes. The HemoCue Glucose 201 RT system is for In Vitro Diagnostic use only. The HemoCue Glucose 201 RT Analyzer is only to be used with HemoCue Glucose 201 RT Microcuvettes. For professional use only.

Technological Characteristics
The technological characteristics for HemoCue Glucose 201 RT system are equivalent to the predicate device. The system consists of an analyzer together with microcuvettes. The microcuvette serves both as a pipette and as a measuring cuvette and is for single-use only. A

blood sample of approximatly 4 µL is drawn into the cavity by capillary action. The chemical reaction in the cavity of the HemoCue Glucose 201 RT microcuvettes has two phases, hemolysis and the glucose reaction. The glucose reaction is a modified glucose dehydrogenase method in which a tetrazolium salt (MTT) is used to obtain a quantification of glucose in visible light. β-D-glucose is transformed to β-D-glucose using mutarotase. Glucose dehydrogenase acts as a catalyst for the oxidation of β-D-glucose, to form NADH, which in the presence of diaphorase produces a colored formazan with MTT. The measurement takes place in the analyzer in which the transmittance is measured and the absorbance and glucose level is calculated. The calibration of the HemoCue Glucose 201 RT system is traceable to the ID GC-MS method. The HemoCue Glucose 201 RT is factory calibrated and needs no further calibration.

Similarities with predicate device

Claim	Similarities
Intended use	The HemoCue Glucose 201 RT and HemoCue Glucose 201 systems are designed for quantitative determination of glucose in whole blood (capillary, venous or arterial blood). Both devices are for professional use only. Both devices are for *In Vitro* Diagnostic use only.
Test principle	Modified glucose dehydrogenase reaction
Result	Quantitative
Positioning	Point of Care
Operating temperature	59°F – 86°F(15°C – 30°C)
Labeling	Equal Directions For Use
Labeling expected results	Fasting glucose values (reference interval): Plasma glucose, adults 74-106 mg/dL (4.5-5.9 mmol/L). For diagnosis of diabetes mellitus, follow local recommendations or use the following value according to WHO and ADA: Fasting plasma glucose, capillary or venous ≥126 mg/dL (≥7.0 mmol/L).
Quality control testing	No external quality control testing is necessary. The systems have an internal self-test.

Assessment of Performance

Studies were conducted in-house, in clinical laboratory settings and point of care centers to demonstrate the performance of the HemoCue Glucose 201 RT system and that the intended user can easily operate the system and obtain results as expected.

Conclusion

The HemoCue Glucose 201 RT system is a convenient method for measuring blood glucose and can be used by typical users and provide clinical results comparable to other test methods in current clinical laboratory and point-of-care practices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

HemoCue AB
c/o Mr. Allan White
Quality System Manager
HemoCue, Inc.
40 Empire Dr.
Lake Forest, CA 92630-2244

SEP - 6 2006

Re: k060765
Trade/Device Name: HemoCue® Glucose 201 RT system
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: LFR
Dated: August 14, 2006
Received: August 14, 2006

Dear Mr. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use

510(k) Number: K060765

Device Name: HemoCue® Glucose 201 RT system

Indications For Use:

The HemoCue Glucose 201 RT system is used for quantitative determination of glucose in whole blood supplementing the clinical evidence in the diagnosis and treatment of patients with diabetes. The HemoCue Glucose 201 RT system is for In Vitro Diagnostic use only. The HemoCue Glucose 201 RT Analyzer is only to be used with HemoCue Glucose 201 RT Microcuvettes. For professional use only.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K060765